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DOCKET NO.: P0453.70115US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sanghvi et al.
Serial No.: 10/821,811
Confirmation No.: 9061
Filed: April 8, 2004
For: PHARMACEUTICAL FORMULATION

Examiner: Not Yet Assigned
Art Unit: 1614

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 10th day of December, 2004.


Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:


- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Sanghvi et al., Applicant

By:


Edward R. Gates, Reg. No.: 31,616
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: P0453.70115US01

Date: December 10, 2004

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Kristin J. Ketelhut

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Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

| <u>Docket No.</u> | <u>Serial No.</u> | <u>Mailing Date</u> | <u>Type of Communication</u> |
|-------------------|-------------------|---------------------|--|
| P0453.70112WO00 | PCT/US2004/010996 | 16 August 2004 | International Search Report and Written Opinion |
| P0453.70115WO00 | PCT/US2004/010997 | 31 August 2004 | International Search Report and Written Opinion |
| P0453.70116WO00 | PCT/US2004/010998 | 1 September 2004 | International Search Report and Written Opinion |

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

Serial No.: 10/821,811
Conf. No.: 9061

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Art Unit: 1614

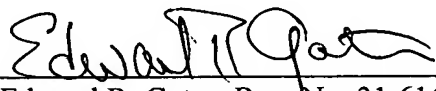
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

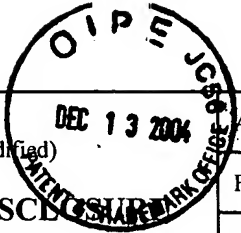
Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Sanghvi et al., Applicant

By: 
Edward R. Gates, Reg. No. 31,616
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600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: P0453.70115US01
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|---|---|-----------------------------|-----------------------------------|
| FORM PTO-1449/A and B (Modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | APPLICATION NO.: 10/821,811 | ATTY. DOCKET NO.: P0453.70115US01 |
| | | FILING DATE: April 8, 2004 | CONFIRMATION NO.: 9061 |
| | | APPLICANT: Sanghvi et al. | |
| | | GROUP ART UNIT: 1614 | EXAMINER: Not Yet Assigned |
| Sheet | 1 | of | 1 |

U.S. PATENT DOCUMENTS

| Examiner's Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication or of issue of Cited Document MM-DD-YYYY |
|---------------------|----------|----------------------|-----------|---|--|
| | | Number | Kind Code | | |
| | A55 | 5,804,595 | | Portoghese, <i>et al.</i> | 09-08-1998 |
| | A56 | 5,866,154 | | Bahal, <i>et al.</i> | 02-02-1999 |
| | A57 | 2003-0022909 | A1 | Moss, <i>et al.</i> | 01-30-2003 |
| | A58 | 2003-0124086 | A1 | Bentley, <i>et al.</i> | 07-03-2003 |
| | A59 | 2003-0191147 | A1 | Sherman, <i>et al.</i> | 10-09-2003 |

FOREIGN PATENT DOCUMENTS

| Examiner's Initials | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document (not necessary) | Date of Publication of Cited Document MM-DD-YYYY | Translation (Y/N) |
|---------------------|----------|-------------------------|-------------|-----------|---|--|-------------------|
| | | Office/Country | Number | Kind Code | | | |
| | B28 | CA | 2,064,373 | | Lilly (Eli) and Company | 09-30-1992 | |
| | B29 | EP | 506,468 | A1 | Eli Lilly and Company | 09-30-1992 | |
| | B30 | EP | 643,967 | A2 | Euro Celtique S.A. | 03-22-1995 | |
| | B31 | WO | 01/32180 | A2 | Rodeva Limited | 05-10-2001 | |
| | B32 | WO | 02/098422 | A1 | University of Chicago | 12-12-2002 | |
| | B33 | WO | 03/032990 | A2 | Shearwater Corporation | 04-24-2003 | |
| | B34 | WO | 2004/014291 | A2 | Moss | 02-19-2004 | |

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials | Cite No | Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published. | Translation (Y/N) |
|---------------------|---------|---|-------------------|
| | C147 | FARTHING et al., New drugs in the management of the irritable bowel syndrome. Drugs. 1998 Jul;56(1):11-21. Review. | |
| | C148 | FINGL et al., Chapter 43: Laxatives and cathartics. <i>In</i> Pharmacological Basis of Therapeutics. 1980: 1002-5. | |
| | C149 | SCHUBERT-ZSILAVECZ et al., Das reizdarmsyndrom irritable bowel syndrome. Deutsche apotheker zeitung. 2002 Aug 22; 142(34): 40-9. | Yes |
| | C150 | TALLEY et al., Pharmacologic therapy for the irritable bowel syndrome. Am J Gastroenterol. 2003 Apr;98(4):750-8. Review. | |
| | C151 | THOMPSON et al., Laxatives: clinical pharmacology and rational use. Drugs. 1980 Jan;19(1):49-58. Review. | |

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|-----------|------------------|
| EXAMINER: | DATE CONSIDERED: |
|-----------|------------------|

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. __, filed __, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]